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DOCTORAL THESIS SUMMARY

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DOCTORAL THESIS SUMMARY

Contribuții la proiectarea și optimizarea structurală a unui braț bionic realizat prin tehnologii de fabricație prin adiție
Contributions to the design and structural optimization of a bionic limb made with additive manufacturing technology

Doctoral field – Industrial Engineering

DOCTORAL COMMETTE

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Contents

Keywords: bionic arm, upper limb prostheses, additive manufacturing technologies, proprioceptive system, low-cost prostheses.

CHAPTER 1. CLASSIFICATION OF THE THESIS

This chapter establishes the context of the research in this paper. The general objective and the specific objectives assumed are presented. The types of upper limb prostheses studied in the thesis are presented. A SWOT analysis of the prosthetics industry sector is being conducted.

Throughout the work, the aim is to design a bionic arm and manufacture it with additive manufacturing technologies. The aim is to establish a final prototype, through the physical-mechanical validation of the model, studied with the finite element method. The study is meant to make improvements in an expanding field of research. This topic falls under the assisted design of medical devices. It addresses the field of industrial engineering for the purpose of innovation.

In the study of the problem of designing an upper limb prosthesis with additive manufacturing technologies, several branches of engineering and medicine intervene, which determines the multidisciplinary character. For this approach, it is necessary to interconnect several branches of engineering both computationally and experimentally. The general objective of this paper is to establish a design methodology that can lead to the manufacture of the device at a low cost. At the same time, computational calculation methods are identified to help in the development of upper limb prostheses. Scientific contributions in the field of prosthetics using additive manufacturing technologies will be made through the creation of improved geometric and structural models.

The specific objectives of this work are as follows:

1 Study of the literature to ascertain the trends recorded, both technically and commercially. Comparative study of existing devices. Implementation and validation of an algorithm for the selection of variants of interface components, functional components, alignment components, structural components and finishing components in order to choose the optimal constructive variants. In this regard, existing constructive variants will be studied.

2 Modelling and study with parametric design of virtual prototypes. Parameterized geometric modelling of a virtual model of upper limb prosthesis with the implementation of the algorithm for the selection of constructive variants in order to detect and remedy design errors. The geometric model will have the function of generating geometry starting from the size dimensions of the healthy limb.

3 Structural study with the finite element method. Implementation and validation of a module for calculating the mechanical-structural model of the prosthesis in order to determine the stresses and reduce the scrap following manufacturing. The structural model will be established based on the parameterized geometric model. We will work with several load cases to facilitate the selection of the optimal variant.

4 Study on the improvement of the proposed model. Design for Manufacturing and Assembly Analysis (DFMA).

5 Study on the proprioceptive system. Development of methods to adapt the system to the absence of the upper limb with the help of virtual tools.

6 Manufacturing of devices resulting from modeling and analysis, using FDM additive manufacturing technologies. Implementation and validation of the experimental prototype of the prosthesis as a result of the implementation of the algorithm for the selection of the constructive variants, the realization of the geometric model and the results of the structural analysis for addition manufacturing. Implementation of the production automation algorithm.

7 Study on the selection of the optimal material for the manufacture of the prosthesis using the multicriteria decision matrix.

8 Making an experimental physical model. Modeling and adaptation for 3D printing of a prototype prosthesis to serve the application of the methodologies proposed in this work

9 Conducting a study to find out the level of acceptance of the proposed prototype both from the position of the prosthesis wearer and from the point of view of interaction with a person, wearing the prosthesis.

10 Performing an experiment to determine the intensity of the current when operating the device. Making a series of measurements to determine the current curves during the positioning of the prototype prosthesis in key positions of its operation.

11 Obtaining low-cost solutions for wide access. The design approach will focus on the accessibility of the device in terms of cost.

12 Study of the behavior of the prototype to bioelectric drive.

The latest research in the field, although it has innovative results, has not implemented the full capacity of Computer Aided Engineering (CAE) and can benefit even more from the development of additive manufacturing technologies. The impact that this research project can have on the field consists in the implementation of an improved methodology of use offered by the CAE. In the design and manufacture of medical devices is a place that can be occupied by this research project. This research project proposes the application of CAE and Additive Manufacturing Technologies (AM) for the field of industrial engineering with medical applications

Expanding this field of knowledge will enable innovation and the design of superior medical products. The result of the research will be a medical device and a series of design methodologies for additive manufacturing in industrial engineering with medical applications. Given the experience of using CAE tools, its application in medical engineering can generate new useful information for the design process in this field.

CHAPTER 2. ASPECTS OF THE CURRENT STATE OF RESEARCH IN THE FIELD

This chapter defines, classifies and presents the functions of upper limb prostheses. It also presents an extensive study of the current state based on the study of the specialized literature in the field.

The development of commercial prostheses and additive manufacturing has given rise to low-cost transient partial hand prostheses. At first, they're a shy presence, but as next-gen technology evolves, they're creeping into the realm of low-cost devices as well. Moreover, as with commercial devices, we may see multidisciplinary teams formed to prescribe a transitional prosthetic to the patient before receiving the commercial one. As a result of the development of sensors, we are likely to see innovative solutions for sensing technology. Accordingly, more research projects will be developed into practical applications of transitional prostheses based on feedback.

One of the challenges of choosing low-cost 3D printable transitional hand partial prosthetic devices is the plethora of databases available. In addition, the large number of results and duplicates found can introduce a higher level of difficulty in choosing. Consequently, specialists can rely on synthesis papers like this thesis to narrow down the search for their patients. Fortunately, there are also several selective content platforms. The Enable community catalogues and the NIH 3D printing exchange are such examples.

The small number of results in clinical trials, as well as the lack of literature in the field of testing such devices, makes them more difficult to recommend. The ability to differentiate between these types of devices is currently based on personal experience and not on experimental results. Such limitations, along with others signalled by similar work, pave the way for future research and development.

CHAPTER 3. COMPARATIVE STUDY OF THE PERFORMANCE OF UPPER LIMB PROSTHESES

This chapter presents a study on existing prostheses. Their operation is described. The main functions are listed. Finally, a comparative study of the prostheses is carried out. The performance of the most used upper limb prostheses was analysed. In Table 0.1 the comparative study is presented.

Table 0.1 Comparative study

No	Name	Level prosthesis	Engine
1	Phoenix hand V3	Under the wrist	Manual
2	Dextra	Above the wrist	DC motors
3	Brunel	Above Wrist	Actuators
4	HRI	Experimental	Multiple motors
5	InMoov	Experimental	Multiple motors
6	PROTO1	Experimental	Multiple motors

7	Naked Prosthetics	Multiple	Manual
8	Zeus	Above Wrist	Servo motors
9	X-limb	Above Wrist	Motors
10	Taska	Above Wrist	Actuators
11	Nexus	Above Wrist	Actuators
12	Hero	Above Wrist	Actuators
13	TrueLimb	Above Wrist	Actuators
14	Bebionic	Above Wrist	Actuators
15	Victoria	shoulder	Manual

CHAPTER 4. DESIGN OF A PARTIAL PROSTHETIC HAND

Anthropomorphic design requires a high degree of complexity in both the structure and the operation of the human hand. The degree of articulation influences the performance of prosthetic devices [1].

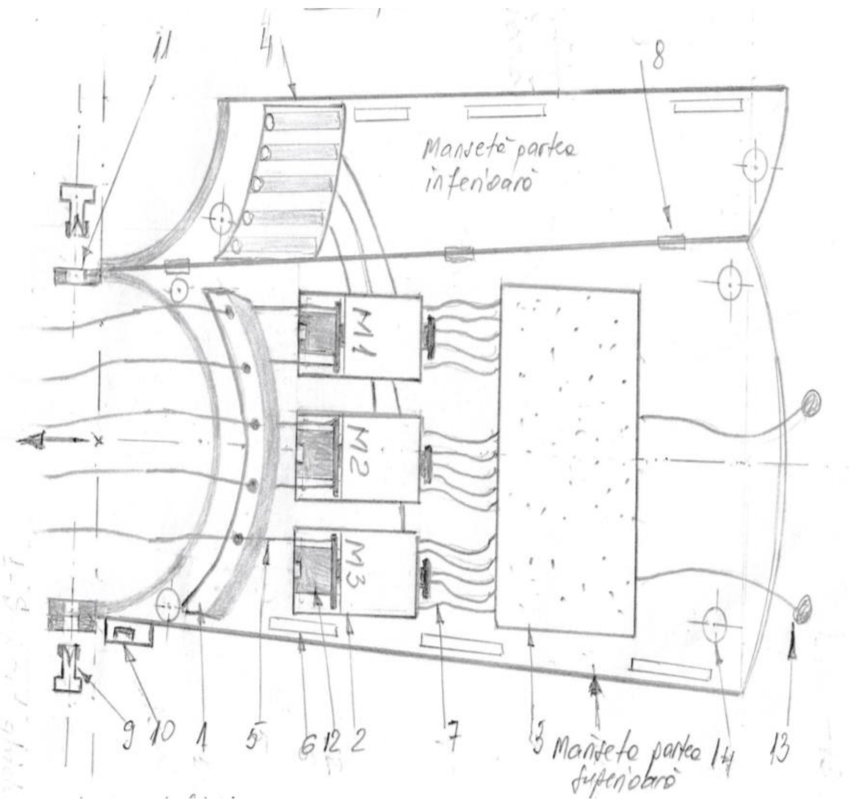

Figure 0.1 Conceptual design of an upper limb prosthesis cuff

where: 1- drive cable guide support; 2- motor set (fingers 1/2, 3/4, 5); 3- electronic board; 4- electric battery; 5- finger drive cable; 6- fixing hole for the fastening straps; 7- motor/plate electrical cables; 8- hinges; 9- Palm grip pin; 10- locking device; 11- palm grip hole; 12- Finger cable winding spool; 13- actuator sensors; 14- External case clamping supports.

During this chapter, a first conceptual design was made. Several conceptual errors were found, and the proposed design was fixed. When transposing the sketched device into CAD, certain errors in the shape of the intersections between the moving components were discovered. Bugs that were fixed leading to the first version of the 3D model of the proposed human upper limb device.

CHAPTER 5. STRUCTURAL ANALYSIS USING THE FINITE ELEMENT METHOD

This chapter presents the structural study of the prosthetic assembly. The numerical calculation was performed followed by the computerized structural analysis using the finite element analysis or method. The diagram in Figure 5.2 was used.

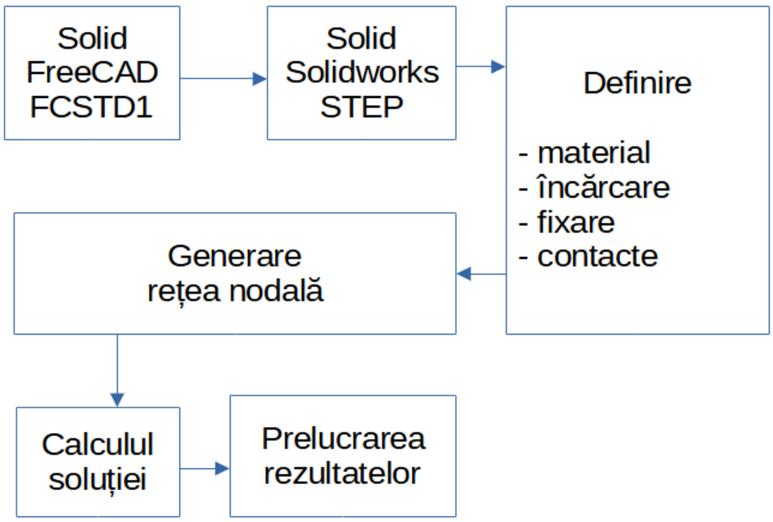

Figure 0.2 Diagram of the structural study

The idea presented for this new type of prosthesis is original, finding no study on partial hand prostheses with both external and body actuation.

An electrically powered prosthesis may be more useful than a body-operated prosthetic device, but when the battery is depleted, the utility advantage balances back to a body-operated device. So, a combined electric and body powered device is ideal. Design choices for the embodiment of the idea were made to speed up the development of the model. The anthropomorphic and bio-inspired approach was used to obtain a good model base.

The results of the static study depend on the yield of the ABS material. Some technical reports propose 60 MPa, while more conservative studies propose 40 MPa; these values correspond to a load between 10 N and 15N for the model proposed in the thesis.

The results of the fatigue test can provide an estimate of the life of the prosthesis. The estimated lifespan of 1 year is based on the number of cycles until complete deterioration.

CHAPTER 6. DESIGN FOR MANUFACTURING AND ASSEMBLY OF A BIONIC ARM

Design for manufacturing and assembly DFMA allows for the optimization of product development projects. This is due to the simultaneous consideration, during the design phase, of the assembly and manufacturing processes.

An important consideration in design, especially for the field studied, is concurrent engineering. This ensures a design methodology based on close communication throughout the project of the main participants in product development.

Programs that implement methodologies for the design and optimization of industrial products help to obtain high-performance products. Production, assembly, material expenses and all the elements that enter the product development process can be optimized.

Although DFMA design programs are very useful, they cannot be applied to all industrial processes. However, new versions of them appear annually and become more and more useful in the design process.

In working with the DFM sub-programme, some shortcomings were observed regarding the fact that it does not have the module for the analysis of manufacturing costs for 3D printing. Which is why a program was made in Microsoft Excel to compensate for this lack of functionality. The DFM sub-programme can also be improved in terms of design rules. The DFMPRO subprogram available for SolidWorks, allows in addition to warning the violation of design norms, which is also done by DFMA, to indicate specific norms with the possibility of redoing the parametric model and reanalysis for a certain manufacturing process.

In the implementation of the DFM process for the upper limb prosthesis, the number of parts was reduced by 27, the number of operations and the assembly expenses were reduced by 10% by joining the cuff and motor support elements. This can be considered an innovative design solution.

By using the DFM methodology, the expenses derived from the production of the upper limb prosthesis were compared in the case of several industrial manufacturing processes. The methodological functionality has been improved, as the DFMA program does not have an algorithm for calculating manufacturing expenses. A tabular calculation was implemented to be able to compare the expenses between the different industrial processes.

Socially, 3D printed upper limb prosthetic devices improve the quality of life for amputees. This research is dedicated to improving prosthetic design to empower people with limited access to health insurance. There are estimates of 3-4 people per 100,000 who suffer from limb loss due to amputation [2]. Although these prostheses are typically used as transitional devices, low-income households have no choice but to use them as end devices. In addition, 3D printed prostheses are also used in underdeveloped countries and war zones. Although neither the available studies nor the companies' policies are sufficient, the research effort is trying to improve devices through projects such as this one.

CHAPTER 7. STUDY ON PROPRIOCEPTIVE SYSTEMS

Recognition of behaviour patterns is used to control bioelectrical prostheses. Although there is a significant amount of research in EMG electromyography, few studies are being conducted on virtual training with prosthetics. Virtual testing can be a solution for the further development of prostheses. The goal was to develop a way to train patients. A human hand was modelled using Autodesk Maya. The model was then arranged and prepared for animation. The animated loops of the main gestures were controlled with keyboard shortcuts assigned in the Unity environment. A virtual hand system has been developed that can be controlled using the computer keyboard. Patients who need training with EMG can benefit from the use of a sensory bracelet with the proposed system.

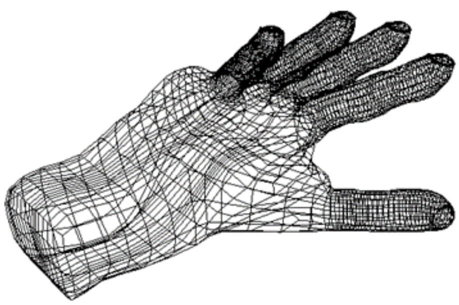

Figure 0.3 The first virtual hand version

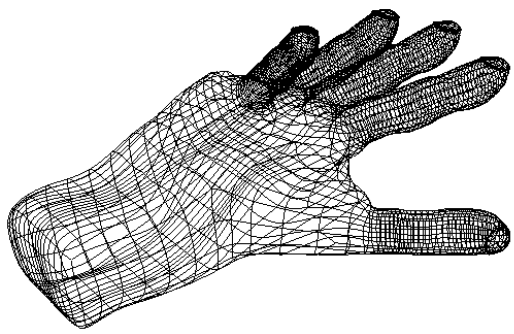

Figure 0.4 Model after topology optimization with hole removal and triad/quad removal

Compared to [3], the study considers the equipment needed to perform experiments using 3D systems, rather than 2D systems presented in the cited paper. Regarding the work of Mutlu et al [5], the experiments included 2 people who felt the actions of one as feedback for the other person. In the case of this paper, the system transmits the feedback from the screen to a virtual hand model. Like [9], a virtual hand was modelled to help research the improvement of proprioceptive feedback for prosthetic users. Although the model described here is not as detailed as that of [8] and [10], the resulting application is suitable for proprioceptive hand training.

Typically, we find research on topological optimization either when it comes to finite element analysis [18] or in the case of design preparation for additive manufacturing [4]. However, in this case it was used to develop a virtual model and improve proprioceptive feedback while reducing the uncanny valley effect [5]. The uncanny valley effect occurs when a robot tends to reach the point of perfect human similarity but fails. Thus, the presented model benefited from topological optimization adapted from other fields.

The human proprioceptive system is a mechanism that with the loss of limbs maintains their presence in memory. Thus, the patient must be educated, to be able to adapt to the new conditions. For this purpose, a virtual model was developed to train patients with missing limbs to be able to use prostheses later. Since the model does not have to be identical to the patient's native hand, but must broadly respect the anatomy of the hand, the model has gone through stages of topological improvement that have led to an improved model for the intended application.

The model was animated in several stages so that the patient could interact with the virtual world through it. This model was made for use with a system of sensors placed on the surface of the patient's skin, in the vicinity of the extremity of the lost limb. Thus, the sensors send signals that enter the processing of the algorithms described in this chapter and because of the patient's gestures, they produce effects on the screen, in the virtual world, on the model made.

Through the proposed system, the re-education of the proceptive system can be achieved so that it can allow the patient a good control of a future prosthesis. The better the system is implemented, the more the patient can adapt to the requirements necessary to be able to control an advanced prosthesis.

In the sections presented, virtual experiments were done to find a balance between high fidelity and topological optimization for a virtual model of a human hand. The first steps towards a proprioceptive feedback system used for patient training and behaviour pattern recognition studies were described. Although quite a bit of work has gone into this work, more work needs to be done to perfect the systems. Limitations include a lack of experimental hands-on work. However, this constitutes an avenue for future research.

CHAPTER 8. DEVELOPMENT OF AN ALGORITHM FOR GENERATING A PROSTHETIC FINGER

Prosthetics, a useful assistive device for patients who have suffered trauma, are characterized by extreme customization, adaptability and complex design. One of the basic principles of having a good prosthesis is an optimized design. With traditional CAD software, what a designer selects will be automatically used and applied to a solid model. However, CAD is not yet advanced enough to provide biomedical designers with a reliable customization tool. A goal of this chapter was to develop a prosthetic device frame for the upper limb finger. A free and freely licensed software environment was used to develop a custom editable finger prosthesis [6]. The implementation was done in the OpenSCAD programming language. The result is a rendering of a fully customizable finger prosthesis. The codebase can be modified to generate new models. The main contribution of the work is the script that provides an interface for prosthetic customization. Such an approach can provide easy-to-use tools for orthopaedic technicians.

Further design improvements and code optimization can reduce the time spent on manufacturing. Most of the time is spent printing the proximal part of the prosthesis for each set. As with the weight and length of the material, an improved weight reduction algorithm can help reduce weight while preserving structural integrity.

The novelty of the analysis presented lies in the integration of CAD and CAM processes to facilitate the use of a design for custom prosthetic 3D printing. The script can be used in connection with a 3D manufacturing device to help users generate custom models without prior design or manufacturing knowledge. Although no additive manufacturing equipment was used in the study, this may serve as a direction for further research in the field.

CHAPTER 9. MULTI-CRITERIA DECISION MATRIX FOR THE CHOICE OF PROSTHESIS MANUFACTURING MATERIAL

Following the analysis with the multi-criteria decision matrix, PLA was chosen as the working material. A list of materials from which the fused filament used in 3D printing is made has been compiled. The properties of these materials were considered, and a decision matrix was constructed for choosing the right material for the manufacturing of the prosthesis.

CHAPTER 10. ADDITIVE MANUFACTURING OF A PROTOTYPE PROSTHESIS FOR THE UPPER LIM

In the context in which partial upper limb prostheses are found in simplified form with body actuation, a prosthesis was designed and manufactured by addition that combines the mechanical body type actuation with the external electrical one. In the following subchapters, the design and manufacture of the parts was described, as well as the assembly and mode of operation, but the calculation of the expenses with these stages was also highlighted.

In a 2021 study [7] it is shown that the permissible tension of the PLA material decreased by 36% and the print time of the specimen also increased when its position was changed from the position with the largest horizontal gauge size to the vertical position.

More recently, the authors of the study [8] explained how a gripping mechanism made of TPU material with a rectangular matrix pattern allows it to grasp objects of various shapes and sizes. They claim that by using Nylon Carbon 12 material for stiffer parts such as the rack wheel, the entire device can be manufactured through additive technologies.

A possibility for improving the performance of materials used in 3D printing, such as PLA, is described in paper [9]. By exposing the workpiece to a temperature of 55 degrees at a pressure of 15 bar, improved modulus of elasticity and tear strength can be achieved. In addition, in the paper [10] it is suggested that a prototype part can become a functional part, by subjecting it to heat treatment. An improvement in fatigue stress performance of 1.25 times greater than without heat treatment was achieved. The variation in the thickness of the molten filament also influences isotropy. In the paper [11] microscopic optical analysis and statistical analysis are used to determine the variation in the thickness of the extruded filament. It is proposed to change the settings in the CAM program to achieve a homogeneous and constant thickness of the filament thickness.

Improving the performance of 3D printed parts can also be achieved by increasing the complexity of the interior geometry. Paper [12] describes the geometry used as having minimal periodic surfaces. In the study, the internal structure was modeled using the parametric design program Rhino together with Grasshopper. The effectiveness of the proposed design was virtually tested using the voxel-print plugin for ABAQUS FEM where non-linear finite element analysis was used, managing to validate the results obtained virtually with experimental data. The influence of interior geometry on the mechanical performance of parts made of PLA was also studied in the paper [13]. In this study, ANSYS was used to simulate the effects of the internal structure, and for experimental validation a universal mechanical performance testing machine was used. The same principle was followed in the paper [14] where a matrix model was designed aiming to reduce the fraction of the contact surface. In this study, SLS technology with PA12 was used as a working material for the manufacturing of a prosthesis. Rhino is also used to generate geometry and then Autodesk Inventor is used to export SLS. The resulting mathematical model was implemented in ANSYS so that flexible and lightweight structures for medical applications could be generated.

The choice of material can also contribute to improving the mechanical performance of parts manufactured by FFF technology. A better option than PLA or other simple materials is reinforced or composite material. Paper [15] describes the integration of additional reinforcing materials into filaments for FFF fabrication.

Making the final 3D model and preparing it for addition manufacturing allowed the production of the first prototype of the proposed device. The device was assembled and the expenses were centralized.

CHAPTER 11. AESTHETIC ASPECTS AND INTERACTION WITH ROBOTIC UPPER LIMBS WITH EFFECTS ON DESIGN AND OPERATION

The field of upper limb prostheses for transitional purposes has a considerable presence in the literature and this is mainly caused by the increased accessibility to 3D printers for additive manufacturing and the openness to include this in the medical field as an intermediate step towards obtaining a commercial prosthesis.

In the present study, a 3D printed prosthesis for the upper limbs used for transition purposes by patients with partial disarticulation of the upper limbs was used. The device uses a mixture of plastic parts and standard metal parts. Metal parts are mostly fasteners and springs. Fasteners are standardized parts. The device also uses a set of electric motors for external drive purposes. The device is hybrid, being both body-powered and externally powered. Although this is only a prototype, the survey is conclusive because it can further improve the device. However, this does not mean that the results will influence the overall design of the prototype considered. In addition, we must consider the relatively small number of respondents, only 113 participants. Also, the group of participants consisted mostly of students with limited experience in industrial design.

From the results of the 4-section survey we can consider some ideas about the visual appeal of the prototype considered. We can also certainly draw some initial conclusions about the problem of plastic versus metal prostheses. Finally, we can extract some knowledge about UVE detection that appears in the current survey study.

A fundamental theme that arises in the presented survey is the issue of anthropomorphism or mechanomorphism among prosthetic devices. Although several questions have been raised about this, the issue is still under discussion and may require further debate.

The respondents gave the impression that they are not interested in the material from which the prosthesis is made. It seems that this is not the right question to ask and the problem can be solved because the answers indicate a minimal problem in terms of materials.

Although several questions were intentionally asked in the present survey to measure UVE, it cannot be said with certainty that this occurred in the subjects while participating in the survey. However, this could change if it interacted with the prosthesis in real life. It is not certain, because the survey was done online, and the participants had only one illustrated reference of the prototype considered. This leaves room for further discussion and research needs to be done to assess UVE levels in all robots, but it may require some form of standardisation.

This chapter presents the findings of a survey of engineering students about a prosthetic upper limb device for transitional purposes. The study highlights that visual appeal is important to most respondents, and while they don't mind interacting with an artificial-looking member, they prefer a more realistic-looking device. The question of whether a plastic prosthesis is more visually appealing than a metal one was considered, but however the question was formulated, the general answer was that this issue does not concern respondents as much as the debate about anthropomorphic versus mechanomorphic models. Finally, an attempt was made to detect UVE in the survey presented, and it reflects an intermediate (neutral) position between attraction (strong agreement) and repulsion (disagreement), with a tendency towards disagreement regarding comfort (section 1) and emotional reaction (section 2), which measures a reduced presence of the UVE effect. There is no need to consider either metal or plastic, but there is an important effort that needs to be made to improve the appearance to be as anthropomorphic as possible. The EVU could have been more highlighted if a more interactive survey had been conducted. An improved version of the survey, along with a hands-on session with people interacting with robotic hands or prosthetic devices, would lead to firmer conclusions. Or even better, organizing a session or workshop involving amputees to interact with both survey respondents and researchers to lead to a better grasp of what is important to all participants.

CHAPTER 12. TESTING THE PROTOTYPE AND OBTAINING EXPERIMENTAL DATA

To detect the functioning of the experimental prototype, a series of attempts were made. For these, a set of sources for powering electronic equipment, a laptop for controlling equipment and a set of other useful tools for electrical and mechanical adjustment were used.

In this chapter, an experimental bench was made to test the behaviour of the prosthesis prototype to the absorption of current from the network. For this, 2 adjustable voltage sources connected to the local grid were used. With their help, it was possible to measure the intensity of the current needed by the motors when they were driven to position the prosthesis.

The prototype was operated using a laptop and the data provided by the power supplies when operating the prosthesis was recorded. Also, throughout its operation, the device was calibrated using adjacent tools such as the multimeter.

An experiment was carried out to test the drive of the proposed prototype. The bioelectric sensor was mounted on one of the control boards and the prosthesis motors were connected to the second development board. The 2 boards communicated via Bluetooth Low Energy – BLE to eliminate disturbances in the system. The use of the 2 control boards was chosen to ensure galvanic isolation.

CHAPTER 13. CONCLUDING THOUGHTS AND PERSONAL CONTRIBUTIONS

This chapter presents a summary of the main contributions. The final considerations are presented. Finally, it reflects on further research. **Eroare! Fără sursă de referință.** presents a comparative study between the proposed variant and other existing models. The models considered with their properties were as follows: Phoenix hand V3 [16], Cyborg Beast [17], Flexy hand 2 [18], Knicks finger [19], Dextra hand [20], Brunel hand [21], MCP Driver [22], Zeus hand [23], X-limb [24], Taska hand [25], Nexus Covvi [26], Hero arm [27], True Limb [28], Bebionic [29] and Victoria Hand [30].

First, the prototype differs from some of the prostheses in **Eroare! Fără sursă de referință.** by the fact that it has standardized parts or manufactured by 3D printing. At the same time while some devices have either electric or mechanical drive, the proposed variant has both. Hybrid actuation is not common in low-cost transitional prostheses. While studying the literature, hybrid variants have been found only in shoulder prostheses, but these consist of segmenting the prosthesis into 2, a mechanical and an electrical part. In this case, the same prosthesis segment has a hybrid drive variant.

Secondly, from the point of view of the availability of equipment and software packages, the proposed variant is among the few that is developed with the help of a freely licensed CAD package. This Favors subsequent takeover and modification by patients or clinicians.

From the point of view of price, although the proposed variant is more expensive than some of the prostheses compared, it can be considered at a low price. On the one hand, the prosthesis has more functions than cheaper variants. On the other hand, the expenses for obtaining the device are much lower than the price of commercial variants.

The presence of the bearing slewing system and the torsion spring return system allow for safer motion control. This benefit can be considered useful even if the presence of these components increases the weight, complexity and price.

The measured actuation force, although lower than that of commercial prostheses, can be improved. The motors used allow for this flexibility. With a similar format in terms of gauge dimensions, at a slightly higher price, better performance values can be achieved. The problems that may arise, however, from this point of view, refer to the availability of this type of motor in the vicinity of those who want to reconstruct the prosthesis.

Finally, the advantages offered by the device such as the implemented hybrid drive, locking, bearing rotation, torsion spring return systems, can have a much greater impact than the points that still need to be worked on, such as weight, reaction speed, developed and static force.

Final Considerations

The thesis aims to contribute to the assisted design methodology of medical devices by designing and manufacturing a bionic arm in low-cost conditions. Considering the proposed aspects, the aim is to design innovative products in the field of industrial engineering with medical applications.

The general objective of this paper is to establish a design methodology that can lead to the manufacturing of the low-cost medical device. The study of the literature (objective 1) whose fulfilment can be observed, in general, throughout the entire work, and in particular is presented in chapters 2 and 3. During them, the study of the current stage was carried out. The development of commercial prostheses and additive manufacturing has given rise to low-cost transient partial hand prostheses. At first, they are a timid presence, but as cutting-edge technology evolves, it is also transmitted to the field of low-cost devices. Moreover, as with commercial devices, we may see multidisciplinary teams formed to prescribe a transitional prosthetic to the patient before receiving the commercial one. As a result of the development of sensors, we are likely to see innovative solutions for sensing technology. Consequently, more research projects will be developed into practical applications of transition prostheses based on the adjustment and response loop.

The parameterized geometric modelling of a prosthetic hand (objective 2) was an objective that considered the possibility of adapting a standard model to the patient according to the individual characteristics of the geometry of the person with disabilities. The evolution of this project is presented in chapter 4.

With the structural study of the proposed model (objective 3) as specific objective 3, a methodology presented throughout chapter 5 was developed. In it, a design was proposed, and it was subjected to virtual tests. The idea presented for a new type of prosthesis is original, finding no study on partial hand prostheses with both external and body actuation. The results of the static study depend on the yield of the ABS material. Some technical reports propose 60 MPa, while more conservative studies propose 40 MPa; these values correspond to a load between 10 N and 15N for the proposed model.

To improve the proposed model (objective 4), a study was carried out to develop the prosthetic design by adapting the DFMA methodology to the field considered. Programs that implement methodologies for the design and optimization of industrial products help to obtain high-performance products. It is possible to optimize production, assembly, material expenses and all the elements that enter the product development process These are described in chapter 6 of this work. In chapter 6, the potential of the DFMA methodology on the studied field was studied and an application methodology was proposed. Design for manufacturing and assembly DFMA allows for the optimization of product development projects. This is due to the simultaneous consideration, during the design phase, of the assembly and manufacturing processes. An important consideration in design, especially for the field studied, is concurrent engineering. This ensures a design methodology based on close communication throughout the project of the main participants in product development. The DFMA study and the application of the algorithm for the proposed project also contributed to the achievement of objective 11 of the present work.

The study of the proprioceptive system (objective 5) was carried out by composing a set of algorithms that serve to retrain the proprioceptive system described in chapter 7 of this work. Through the proposed system, the proprioceptive system can be re-educated so that it can allow the patient a good control of a future prosthesis. The better the system is implemented, the more the patient can adapt to the requirements necessary to be able to control an advanced prosthesis.

The development of an algorithm for automatic production (objective 6) was first achieved by designing an algorithm for customizing a standard prosthesis model. To this algorithm was added another one that takes the model and sends it to manufacturing by addition. As described in chapter 8 and in order to achieve specific objective 6, a process has been carried out that receives the dimensions, generates the CAD/CAM model and can send the newly created and adapted prosthesis for the patient for manufacturing.

The choice of the manufacturing material (objective 7) was made by drawing up a list of materials used in additive manufacturing. The multi-criteria decision matrix was made which, considering the physical-mechanical properties of the materials, allowed the right choice for the intended application. The process is described in Chapter 9 in detail.

To make an experimental physical model (objective 8), a prototype was fabricated by addition and mounted that can be used in further research to improve the prosthetic design proposed in this work. This is described in Chapter 10, which also presents the calculation of prototyping expenses (objective 11), which reveals the costs involved and emphasizes the classification of the prototype in the group of low-cost devices.

During chapter 11, the level of acceptance of the proposed prototype (objective 9) was studied through a survey. This was achieved towards the fulfilment of specific objective 9 where the emphasis was placed on what could still be improved in the prototype and its level of acceptance.

In chapter 12 the prototype was subjected to a series of experiments (objective 10) consisting of electric drive. The current intensity was monitored during operation. The values were recorded and the curves of the graphs describing the measured current at the key points of the device's operation were raised. At the same time, the behavior of the prototype at bioelectric drive (objective 12) was also studied.

Original contributions

Theoretical contributions

1. First, an extensive bibliographic study was carried out. This can be seen throughout the work. The purpose of conducting this study was to acquire a good understanding of the field studied. International databases such as Scopus, PubMed and DOAJ were consulted. Standards from the ASRO library have been studied. Analysed patents from the Google Patents library were also cited.

2. Secondly, a comparative study of the performance of upper limb prostheses was carried out.

Modelling-simulation contributions

3. A standard model of partial hand prosthesis has been designed. A licensed free program with open access to the source code was used. A complete parametric table has been attached to this model. The table allows the regeneration of the geometric model for its adaptation to the diverse needs of patients. In other words, it can serve to generate partial upper limb prosthetics. This is described in Chapter 4.

4. At the same time, the numerical calculation for determining the stresses occurred in the tensile device was discretized and performed, obtaining values of the order of 0.0958MPa. The device was introduced into the program and structurally analyzed to establish the maximum load. It returned an estimated maximum permissible load of 12 N of load. Based on the fatigue analysis performed we can see the maximum life cycle set to ~45000 cycles. We can estimate from this a life of 1 year without cracks and 5 years with periodic maintenance. The course of the studies is illustrated in chapter 5 of the paper. The idea presented for a new type of prosthesis is original, finding no study on partial prosthesis of human upper limbs with both external and body actuation. An electrically powered prosthesis may be more useful than a body-operated prosthetic device, but when the battery is depleted, the utility advantage balances back to a body-operated device. So, a combined electric and body powered device is ideal.

Methodological contributions

5. Another contribution, presented in Chapter 6, is the development of a design methodology based on DFMA. In working with the DFM subprogram, certain shortcomings were observed regarding the fact that it does not have a module for the analysis of manufacturing expenses for 3D printing, which is why a program was developed in Microsoft Excel to compensate for this lack of functionality. In the implementation of the DFM process for the upper limb prosthesis, the number of parts was reduced by 27, the number of operations and the assembly expenses were reduced by 10% by joining the cuff and motor support elements. This can be considered an innovative design solution with a direct result in a decrease in costs. By using the DFM methodology, the expenses derived from the production of the upper limb prosthesis were compared in the case of several industrial manufacturing processes. The methodological functionality has been improved, as the DFMA program does not have an algorithm for calculating manufacturing expenses. A tabular calculation was implemented to be able to compare the expenses between the different industrial processes.

Experimental contributions

6. The next contribution is the development of algorithms for improving the proprioceptive system in people with missing upper limbs. The process described in chapter 7 includes the creation of a virtual hand model, its topological optimization, the creation of a system that allows the interaction of the patient with the virtual model through a human-machine interface and the description of their operation.

7. Another contribution is the development of a system for the automatic design and manufacturing of a prosthesis. The process described in chapter 8 allowed the development of

algorithms capable of making a physical model starting from input data provided by a technician-operator.

8. Finally, a multi-criteria decision matrix study was carried out, which resulted in the optimal material for printing the prosthesis as PLA. This process is described in chapter 9 of the paper.

9. In addition, the manufacturing by addition was carried out and a prototype of a prosthetic model was mounted, which presents some proposals that do not exist in the current models. The position lock system is one of the systems that are not present in many of the current variants of transitional FDM manufactured prostheses. The pretensioning system is moved from the cuff to the finger subassembly, which is also original. At the same time, the possibility of either mechanical or electric actuation by implementing a hybrid system is something original, as such projects are not found in the literature. The device uses 3D printed elements and standardized assembly, sealing, and mechanical transmission elements, which resulted in a prototype being obtained at a low cost. Chapter 10 exemplified the calculation of manufacturing technology expenses and the final cost of the prototype.

10. Moreover, a study was conducted to test the level of acceptance of the prototype among people, both in terms of personal use and in terms of interaction with someone who uses this device.

11. The values of the current intensities during the operation of the prototype were determined experimentally. The current curves continued to be raised in order to position the prosthesis in the ways in which it would be used. The maximum intensity of the current in the circuit has been set.

Contributions to the dissemination of research results

12. Finally, the results of the corroborated research were disseminated, materialized in scientific articles presented at international scientific events and published in the volumes of internationally appreciated scientific journals.

Further research and insights

To obtain a clearer picture of the field, a more extensive documentation is necessary. Thus, the study of the current stage by consulting scientific journals and participating in scientific conferences in the field will constitute levels for further research. Expanding searches in Nature and Science databases can be a starting point. Making documentation trips to internationally renowned laboratories in the field can also be an option.

The parametric modelling of a generic prosthesis model can be improved. In this sense, the use of generative design and the achievement of ergonomic shapes that meet the needs of patients can be pursued. This involves studying advanced design programs and methodologies such as free and curve-based modelling offered by the Rhinoceros 3D program.

To improve the structural analysis, it is intended to consider kinematic simulation studies and improve the mechanisms in the device's composition. These integrated simulations can offer the possibility of a broader analysis of the project. In order to obtain new geometric models, it is possible to start from an extensive simulation with several levels of studies.

The functionality of the DFM sub-programme can also be improved in terms of design rules. The DFMPRO subprogram available for Solidworks allows, in addition to warning the violation of design norms, which is also done by DFMA, to indicate the specific norms with the possibility of redoing the parametric model and reanalysis for a certain manufacturing process. This capability will allow for better synchronization between the concept and the manufactured variant.

Proprioceptive systems can influence a patient's decision to use a prosthesis. Thus, by studying and improving the algorithms that are the basis of their re-education applications, it constitutes an important level of further research. At the same time, EMG sensors and electronic systems for detecting movement intentions can be improved, thus having better equipment and experience in working with prostheses can be better.

The algorithms for the automatic design and manufacturing of prostheses can be considered a step to be developed in order to improve the practical realization of these prostheses, starting from a better graphical interface, a code base that can be improved and integration with the work machines in the offices of the future beneficiaries of this system.

The development of questionnaires that reveal people's opinion about prostheses would lead to a better design aimed at increasing the acceptance of prostheses. A multidisciplinary team and a broader study of the literature could lead to good results in this regard in the future.

The selection of manufacturing materials for prostheses can be expanded with new materials. And the selection method can include several criteria for classifying materials. Thus, in this regard, research can continue to choose materials, to add more materials, to extend to more manufacturing processes and improve the performance of low-cost prostheses.

In terms of experimental evaluation, several sets of tests are needed to bring the prototype to the level where it can be used by patients. Access to more advanced manufacturing equipment, but also an in-depth study on the possibilities of improving the device, will allow the improvement of the proposed prosthetic device in the future.

List of published scientific papers

Works in the field of doctoral studies

1. ***Răduică F.-F.***, Simion I., Ioniță E., 2021, *A Study on Parametric Design of Line Tendon Based Prosthetic Finger Using Programming Techniques*, Journal of Industrial Design and Engineering Graphics, ICV 96.6, vol. 16, nr. 2, pag, 4-10, Online ISSN 2344-4681, tip document: Articol Jurnal, http://www.sorging.ro/jideg/index.php/jideg/article/view/251/246

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